

Clotrimazole Cream
SDS Revision Date: 07/18/2026

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SAFETY DATA SHEET

Section 1. IDENTIFICATION

Product Identifier used on the label:

Medi ♥ First Aid Antifungal Cream Clotrimazole 1%

Other means of Identification:

Cartons: 52128 (1 Pk / 1 oz Tube), 52170 (4 Pk / 1 oz Tube), 52169 (6 Pk / 1 oz Tube)

Recommended use of the chemical and restrictions on use:

- Over the counter (OTC) antifungal drug for the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), and the ringworm (tinea corporis).

Restrictions on use:

- For external use only
- Use only as directed on the product label
- Avoid contact with eyes
- Keep out of reach of children

Chemical family

- Imidazole antifungal

Name, address, and telephone number of the supplier (Distributor/Repackager):

Medique Products

17080 Alico Commerce Ct. Ste 1

Fort Myers, FL, USA 33967

Supplier's Telephone #: 1-800-634-7680

Name, address, and telephone number of the supplier (Manufacturer):

Galentic Pharma (India) Pvt. Ltd.

Plot No. 5-B & 5-C, Sector – III, Kandla SEZ,

Gandhidham, Gujarat – 370230, India Manufacturer's

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture:

- Not classified as hazardous according to OSHA Hazard Communication Standard.

Label Elements:

- None

Hazard Pictograms:

- None

Signal Word:

- None

Hazard Statements:

- Not classified as hazardous.

Precautionary Statements:

Prevention:

- Use only as directed.
- Avoid contact with eyes.
- Wash hands thoroughly after handling.

Response:

- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, obtain medical advice/attention.
- If skin irritation occurs: Discontinue use. If irritation persists or an allergic reaction develops, obtain medical advice/attention.
- If inhaled: Move person to fresh air if respiratory irritation occurs.
- If swallowed: Call a physician or poison center if you feel unwell. If skin irritation occurs, discontinue use and seek medical advice if irritation persists.

Storage:

- Store at 15°C–30°C (59°F–86°F).
- Keep container tightly closed when not in use.
- Keep out of reach of children.

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Disposal:

- Dispose of contents / containers in accordance with local state, and federal regulations.

Hazards Not Otherwise Classified (HNOC):

- None known.

Physical Hazards Not Otherwise Classified (PHNOC):

- None known.

Other Information:

- This product is an OTC antifungal cream intended for external use.
- Direct contact with the eyes may cause temporary irritation.
- Individuals with known hypersensitive to clotrimazole or any component of the formulation may experience localized skin irritation or allergic reactions.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Mixture: Mixture

Chemical Name	Common Name/Synonyms	CAS Number	Concentration
Clotrimazole	Clotrimazole	23593-75-1	1.0% w/w
Macrogol Cetostearyl Ether	Polyoxyethylene Cetostearyl Ether	68439-49-6	Proprietary
Cetostearyl Alcohol	Cetearyl Alcohol	67762-27-0	Proprietary
Mineral Oil	White Mineral Oil	8042-47-5	Proprietary
Methylparaben	Methyl Parahydroxybenzoate	99-76-3	Proprietary
White Petrolatum	Petrolatum	8009-03-8	Proprietary
Propylene Glycol	Propane-1,2-diol	57-55-6	Proprietary
Propylparaben	Propyl Parahydroxybenzoate	94-13-3	Proprietary
Purified Water	Water	7732-18-5	Proprietary

Additional Information

Product Type:

- Mixture.
- The exact concentrations of the inactive ingredients are withheld as trade secret information in accordance with applicable regulations.
- No additional ingredients are present at concentrations requiring disclosure under the OSHA Hazard Communication Standard (29 CFR 1910.1200).

SECTION 4: FIRST-AID MEASURES

Description of First Aid Measures:

Inhalation:

- Inhalation is not an expected route of exposure under normal conditions of use.
- If respiratory irritation occurs, move the affected person to fresh air.
- If symptoms persist, obtain medical attention.

Skin Contact:

- Product is intended for topical use.

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- If skin irritation, rash, or signs of an allergic reaction develop, discontinue use.
- Wash the affected area with soap and water.
- If irritation persists, seek medical advice/attention.

Eye Contact:

- Immediately rinse eyes cautiously with plenty of water for at least 15 minutes.
- Remove contact lenses, if present and easy to do.
- Continue rinsing.
- If eye irritation persists, obtain medical advice/attention.

Ingestion:

- Product is intended for external use only.
- If swallowed, rinse mouth with water.
- Do **not** induce vomiting unless directed by medical personnel.
- Contact a physician or poison center immediately if a large quantity has been swallowed or symptoms develop. Most important symptoms and effects, both acute and delayed:

Most Important Symptoms and Effects, Both Acute and Delayed:

- Temporary eye irritation.
- Mild skin irritation or redness.
- Allergic skin reactions may occur in individuals sensitive to clotrimazole or other formulation ingredients.
- Accidental ingestion may cause gastrointestinal discomfort.

Indication of any immediate medical attention and special treatment needed:

- Treat symptomatically.
- No specific antidote is known.

General Information:

- Show this Safety Data Sheet to the attending physician if medical treatment is required.
- Discontinue use and seek medical advice if signs of an allergic reaction develop.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media:

Suitable extinguishing media:

- Water spray
- Alcohol-resistant foam
- Dry chemical
- Carbon dioxide (CO₂)

Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing agent:

- None known.

Specific hazards arising from the chemical:

- Product is not expected to present a significant fire or explosion hazard under normal conditions of use.
- Thermal decomposition or combustion may produce hazardous gases, including:
 - Carbon oxides CO, CO₂
 - Hydrogen chloride (HCl)

Special protective equipment and precautions for firefighters

- Wear self-contained breathing apparatus (SCBA) and full protective firefighting clothing when fighting a fire involving this material.
- Avoid inhalation of combustion products.
- Cool exposed containers with water spray if safe to do so

Fire-fighting procedures:

- Use standard firefighting procedures
- Consider hazards associated with surrounding materials
- Remove containers from the fire area if it can be done safely.

General fire hazards:

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- Not classified as flammable
- No unusual fire or explosion hazards are known under normal conditions of storage and use

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

- Product is intended for consumer and occupational use under normal conditions.
- Avoid contact with eyes.
- Wear appropriate personal protective equipment when cleaning up large spills.
- Ensure adequate ventilation during cleanup.
- Keep unnecessary personnel away from the spill area.

Environmental precautions:

- Avoid uncontrolled release to the environment.
- Prevent large quantities from entering drains, surface waters, or soil.
- Notify appropriate authorities if a significant release occurs, as required by applicable regulations.

Methods and material for containment and cleaning up:

- Contain the spilled material to prevent spreading.
- Collect bulk material using absorbent material such as paper towels, cloths, sand, vermiculite, or inert absorbent.
- Place collected material into a suitable container for disposal.
- Clean the affected area with soap and water after the bulk material has been removed.
- Dispose of waste in accordance with applicable federal, state, and local regulations.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

- Use only as directed.
- For external use only.
- Avoid contact with eyes, mucous membranes, and broken skin unless directed by a healthcare professional.
- Wash hands after handling unless the hands are the area being treated.
- Do not ingest.
- Keep container tightly closed when not in use.
- Keep out of reach of children.

Conditions for safe storage, including any incompatibilities:

- Keep container tightly closed in a cool, dry, well-ventilated area.
- Protect from excessive heat, freezing temperatures, and direct sunlight.
- Store in the original container.
- Keep away from incompatible materials identified in Section 10.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters:

Occupational Exposure Limits

- No occupational exposure limits have been established by OSHA, ACGIH, or NIOSH for this mixture or its active ingredient, clotrimazole. b

Biological Exposure Indices:

- No biological exposure limits have been established.

Appropriate Engineering Controls:

- General room ventilation is adequate under normal conditions of use.
- Emergency eyewash facilities are recommended where occupational exposure to the product could occur.

Individual Protection Measures:

Eye/Face Protection:

- Not normally required under normal conditions of use.

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Skin Protection:

Hand Protection:

- Safety glasses or chemical safety goggles are recommended when handling large quantities or where splashing may occur.

- Not normally required for consumer use.
- Protective gloves are recommended for prolonged or repeated occupational handling if skin sensitivity develops.

Other Protection:

- Wear appropriate protective clothing as needed to prevent repeated or prolonged skin contact during bulk handling.

Respiratory Protection:

- Not normally required under normal conditions of use.
- If adequate ventilation cannot be maintained during bulk processing, use appropriate respiratory protection in accordance with applicable regulations.

General Hygiene Considerations:

- Wash hands thoroughly after handling.
- Avoid contact with eyes.
- Do not eat, drink, or smoke while handling the product.
- Follow good industrial hygiene and safety practices.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White to off-white cream
Physical State	Semi-solid
Color	White to off-white
Odor	Mild characteristic odor
Odor Threshold	Not available
pH	Not available
Melting Point/Freezing Point	Not available
Initial Boiling Point and Boiling Range	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability (Solid, Gas)	Not applicable
Upper/Lower Flammability or Explosive Limits	Not available
Vapor Pressure	Not available
Vapor Density	Not available
Relative Density	Not available
Solubility	Partially soluble in water
Partition Coefficient (n-octanol/water)	Not available
Auto-Ignition Temperature	Not available
Decomposition Temperature	Not available
Viscosity	Not available
Particle Characteristics	Not applicable (semi-solid mixture)

SECTION 10: STABILITY AND REACTIVITY

Reactivity:

- The product is not reactive under normal conditions of storage, handling, and use.

Chemical Stability:

- Stable under recommended storage conditions.

Possibility of hazardous reactions:

- Hazardous polymerization will not occur.
- No hazardous reactions are expected under normal conditions of use.

Conditions to avoid:

- Excessive heat.
- Open flames and ignition sources.
- Prolonged exposure to direct sunlight
- Freezing temperatures

Incompatible materials:

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- Strong oxidizing agents.
- Strong acids.
- Strong bases

Hazardous Decomposition Products:

- Thermal decomposition or combustion may produce:
 - Carbon oxides (CO, CO₂)
 - Nitrogen oxides (NO_x)
 - Nitrogen chloride

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure:

Eye Contact:

- Direct contact with eyes may cause temporary irritation, redness, or discomfort.

Skin Contact:

- Prolonged or repeated contact may cause mild irritation or allergic skin reactions in sensitive individuals.

Inhalation:

- Not an expected route of exposure under normal conditions of use. Inhalation of mists generated during bulk processing may cause respiratory irritation.

Ingestion:

- May cause gastrointestinal discomfort, including nausea, vomiting, or diarrhea if swallowed. The product is intended for external use only.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:

- Temporary eye irritation.
- Mild skin irritation or redness.
- Allergic skin reactions in susceptible individuals.
- Gastrointestinal discomfort following accidental ingestion.

Delayed and Immediate Effects and Chronic Effects from Short- and Long-Term Exposure:

- No adverse health effects are expected when the product is used as directed.
- Repeated or prolonged skin contact may result in irritation or sensitization in susceptible individuals.

Numerical Measures of Toxicity:

- No toxicological data are available for the finished product.

Clotrimazole (CAS No. 23593-75-1)

Endpoint	Value
Oral LD ₅₀ (Rat)	> 2,000 mg/kg*

*Published literature values may vary depending on study conditions.

Carcinogenicity:

This product is not listed as a carcinogen by:

- OSHA
- IARC
- NTP
- ACGIH

Germ Cell Mutagenicity:

- Not expected to be mutagenic based on available information.

Reproductive Toxicity:

- Not expected to cause reproductive toxicity under normal conditions of use.

Specific Target Organ Toxicity (STOT):

Single Exposure:

- Not classified.

Repeated Exposure:

- Not classified.

Aspiration Hazard:

- Not classified as an aspiration hazard.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:

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- No ecological data are available for the finished product.
- The product is not expected to present a significant environmental hazard when used and disposed of as directed

Persistence and Degradability:

- No data are available for the finished product.

Bioaccumulative Potential:

- No data are available for the finished product.

Mobility in Soil:

- No data are available for the finished product.

Other Adverse Effects:

- No other adverse environmental effects are known.
- Avoid uncontrolled release of large quantities into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Methods:

- Dispose of unused product, contaminated absorbent materials, and empty containers in accordance with all applicable federal, state, and local regulations.
- Do not discharge large quantities into drains, surface waters, or the environment.
- Empty containers may retain product residue and should be handled in accordance with applicable waste management regulations.

Contaminated Packaging:

- Dispose of packaging in accordance with local, state, and federal regulations.
- Recycle packaging materials where facilities are available and appropriate.

SECTION 14: TRANSPORT INFORMATION

Transport Mode	Classification
U.S. DOT	Not regulated as a hazardous material
IMDG (Sea Transport)	Not regulated as dangerous goods
IATA (Air Transport)	Not regulated as dangerous goods

UN Proper Shipping Information:

- UN Number: Not applicable
- UN Proper Shipping Name: Not applicable
- Transport Hazard Class(es): Not applicable
- Packing Group: Not applicable
- Environmental Hazards: Not applicable
- Marine Pollutant: No
- Transport in Bulk (according to IMO instruments): Not applicable

Special Precautions for User:

- Transport in closed, properly labeled containers.
- Protect from excessive heat and freezing during transport.
- Avoid damage to containers that could result in leakage.

SECTION 15: REGULATORY INFORMATION

OSHA Hazard Communication Standard (29 CFR 1910.1200):

- This product is not classified as hazardous under the OSHA Hazard Communication Standard when used as intended.

Toxic Substances Control Act (TSCA):

- All components of this product are listed on, exempt from, or otherwise comply with the requirements of the TSCA Inventory.

CERCLA (Comprehensive Environmental Response, Compensation and Liability Act):

- This product does not contain substances subject to CERCLA reporting requirements at reportable quantities.

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SARA Title III (EPCRA):
Section 302 – Extremely Hazardous Substances

- This product does not contain substances subject to Section 302 reporting requirements.

Section 311/312 – Hazard Categories:

- Not classified as hazardous.

Section 313 – Toxic Chemicals:

- This product does not contain chemicals subject to SARA Section 313 reporting requirements.

State Regulations:
California Proposition 65:

- This product is not known to contain substances listed under California Proposition 65 at levels requiring a warning.

Canadian Regulations:
Canadian Domestic Substances List (DSL):

- All components of this product are listed on or comply with the Canadian DSL.

International Inventories:

The components of this product are reported as present on applicable chemical inventories where required, including:

- TSCA (United States)
- DSL (Canada)
- EINECS (European Union)
- AICS (Australia)
- PICCS (Philippines)
- IECSC (China)

U.S. FDA Regulatory Status:

- This product is an over-the-counter (OTC) first aid antibiotic drug product regulated by the U.S. Food and Drug Administration (FDA) when manufactured, labeled, and distributed in accordance with applicable FDA requirements.

Other Regulatory Information:

- No additional regulatory information is available for the finished product.

SECTION 16: OTHER INFORMATION (UPDATED)

Preparation Date: 1/17/2026

Reviewed Date SDS: 7/18/2026

Revision No. 2

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